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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,047	09/23/2002	Manuel Fresno Escudero	34909-PCT USA 069277.0108	8670
21003	7590	12/01/2005	EXAMINER PAK, YONG D	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			ART UNIT 1652	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/031,047

Applicant(s)

ESCUDEIRO ET AL.

Examiner

Yong D. Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10,12,13,18-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 and 24 is/are allowed.
- 6) ☒ Claim(s) 10,12,13,18-20 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/8/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The amendment filed on August 8, 2005, amending claims 10, 12, 18 and 22 and canceling claims 14, 16-17, 21 and 26-30, has been entered. The supplemental amendment filed on September 6, 2005 has been entered.

Claims 10, 12-13, 18-20 and 22-24 are pending and are under consideration.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on August 8, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Response to Arguments***

Applicant's amendment and arguments filed on August 8, 2005, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-20 and 22-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter.

Claims 18-20 and 22-23, as written, are directed to non-statutory subject matter. Claims 18-20 and 22-23 are broadly drawn to a cell which could still be attached to a human being. Human being are considered non-statutory subject matter. Examiner urges applicants to make appropriate amendment such that the claims do not read on a human being.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 12-13, 18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kutchera et al.

Claims 10, 12-13, 18 and 22 are drawn to a polynucleotide consisting essentially of SEQ ID NO:5 linked to a luciferase gene, vector comprising said polynucleotide and host cell comprising said polynucleotide.

Kutchera et al. (cited on previous form PTO-892 – Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 4816-4820, May 1996) teaches a polynucleotide consisting essentially of SEQ ID NO:5 of the instant invention. Kutchera et al. teaches a 1963 bp fragment of the promoter region of a human COX-2 promoter (-1840 to +123) which encompasses

Art Unit: 1652

SEQ ID NO:5 of the instant invention (-1796 to +104) (abstract, pages 4817-4818). The polynucleotide of Kutchera et al. is linked to a Renilla luciferase gene (pages 4817-4818). Kutchera et al. also teach a cell comprising said polynucleotide (pages 4817-4818). Therefore, the reference of Kutchera et al. anticipate claims 10, 12-13, 18 and 22.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants argue that the polynucleotide of Kutchera et al. does not anticipate claims 10, 12-13, 18 and 22 because the claims do not cover polynucleotides "comprising" or "consisting essentially of" SEQ ID NO:5. Examiner respectfully disagrees. The rejection has been amended. The claims are drawn to a polynucleotide consisting essentially of SEQ ID NO:5. A polynucleotide consists essentially of a nucleic acid sequence when such a nucleic acid sequence is present with a few additional nucleic acids. MPEP 2113.03 states that

"A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format."

Since the polynucleotide of Kutchera et al. is a 1963 bp fragment of the promoter region of a human COX-2 promoter (-1840 to +123) which encompasses SEQ ID NO:5 of the instant invention (-1796 to +104), the polynucleotide of Kutchera et al. consists essentially of SEQ ID NO:5. Therefore the teachings of Kutchera et al. anticipate claims 10, 12-13, 18 and 22.

Hence the rejection is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kutchera et al. as applied to claims 10, 12-13, 18 and 22 above, and further in view of ATCC TIB-152.

Claim 20 is drawn to Jurkat cells comprising a polynucleotide consisting essentially of SEQ ID NO:5 linked to a Renilla luciferase gene.

Art Unit: 1652

The reference of Kutchera et al., as applied to claims 10, 12-13, 18 and 22, teaches a polynucleotide consisting essentially of SEQ ID NO:5 linked to a Renilla luciferase gene, as discussed above. Kutchera et al. also teach that a Renilla luciferase gene linked to the promoter region of human COX can be used to examine transcription levels of the COX gene (page 4818, right column).

The difference between the reference of Kutchera et al. and the instant claims is that the reference of Kutchera et al. does not teach Jurkat cells comprising a polynucleotide consisting of SEQ ID NO:5 linked to a luciferase gene.

However, expression of genes in Jurkat cells are well established in the art. Jurkat cells are commercial available, such as through ATCC TIB-152.

Therefore, combining the teachings of the above three references, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made a Jurkat cell comprising the polynucleotide of Kutchera et al. One of ordinary skill in the art would have been motivated to use Jurkat cells since the cells are easy to grow. One of ordinary skill in the art would have had a reasonable expectation of success in making the cells since the cited references teaches successful expression of genes in Jurkat cells.

Therefore, Kutchera et al. and ATCC TIB-152 render claim 20 *prima facie* obvious to those skilled in the art.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants argue that claims 10, 12-13, 18 and 22 are not obvious because the claims do not cover polynucleotides "comprising" or "consisting essentially of" SEQ

Art Unit: 1652

ID NO:5. Examiner respectfully disagrees. The rejection has been amended. The claims are drawn to a polynucleotide consisting essentially of SEQ ID NO:5. A polynucleotide consists essentially of a nucleic acid sequence when such a nucleic acid sequence is present with a few additional nucleic acids. MPEP 2113.03 states that

"A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format."

Since the polynucleotide of Kutchera et al. is a 1963 bp fragment of the promoter region of a human COX-2 promoter (-1840 to +123) which encompasses SEQ ID NO:5 of the instant invention (-1796 to +104), the polynucleotide of Kutchera et al. consists essentially of SEQ ID NO:5.

Hence the rejection is maintained.

#### ***Requirement for the Deposit of Biological Material***

The Declaration filed on September 6, 2005 satisfies the biological deposit requirements of a cell line having the access number CECT 5145 and ECACC 9903245.

#### ***Allowable Subject Matter***

Claims 23-24 are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak  
Patent Examiner 1652



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